August 18, 2023

DIO Corporation
% Peter Kang
General Manager
DIO USA
2729 Bristol St.
Costa Mesa, California 92626

Re: K220253
Trade/Device Name: Eco Abutment, Multiunit Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 19, 2023
Received: July 19, 2023

Dear Peter Kang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220253

Device Name
Eco Abutment, Multiunit Abutment

Indications for Use *(Describe)*

Indications for Use for Eco Abutment
The Eco Abutment is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.

Indications for Use for Multiunit Abutment
The Multiunit Abutment is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K220253

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1. Device Information

Trade Name: Eco Abutment, Multiunit Abutment
Common Name: Dental Implant Abutment
Classification Name: Endosseous dental implant abutment
Product Code: NHA
Regulation Number: 21 CFR 872.3630
Device Class: Class II
Date prepared: August/18/2023

2. Predicate Device

Primary Predicate

K161655 – On1 Concept

Reference Device

K182194 - UV Active Implant System
K173975 – UF(II) Wide Fixture
K122519 – DIO UF HSA INTERNAL SUB-MERGED IMPLANT SYSTEM
K170608 – UF(II) Implant System
K080559 – DIO SM IMPLANT SYSTEM

3. Device Description

The Eco Abutment is compatible with following Implant system. The Eco abutments cannot be used with implant diameters less than Ø3.8mm.

Manufacturer	Compatible Implant System	510(k) Number	Implant diameter (mm)	Connection type
DIO Corporation	UV Active Implant System	K182194	3.8/4.0/4.5/5.0/ 5.5/5.9/6.4	Internal Hex/Non-hex
	UF(II) Wide Fixture	K173975	5.9/6.4/6.9	Internal Hex/Non-hex
	UF Submerged Implant system	K122519	3.8/4.0/4.5/5.0/ 5.5/5.9/6.4/6.9	Internal Hex/Non-hex
	UF(II) Implant System	K170608	3.8/4.0/4.5/5.0/ 5.5	Internal Hex/Non-hex

The Multiunit abutment is compatible with following Implant system. The Multiunit abutments cannot be used with implant diameters less than Ø4.5mm.

Manufacturer	Compatible Implant System	510(k) Number	Implant diameter (mm)	Connection type
DIO Corporation	UV Active Implant System	K182194	4.5/5.0/ 5.5/5.9/6.4	Internal Hex/Non-hex
	UF(II) Wide Fixture	K173975	5.9/6.4/6.9	Internal Hex/Non-hex
	UF Submerged Implant system	K122519	4.5/5.0/ 5.5/5.9/6.4/6.9	Internal Hex/Non-hex
	UF(II) Implant System	K170608	4.5/5.0/ 5.5	Internal Hex/Non-hex

Eco Abutment is a two-piece abutment. It consists of a base abutment which is used with temporary post, cemented post, angled post and healing cap. The base abutment is first secured to the dental implant with a base screw and the post is secured to the base abutment with post screw. The Eco Abutment has 4.5, 4.8, 5.5 and 6.5 of diameter and consists of 0, 6, 12 and 18 degree.

The Multiunit Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single unit loading (i.e., crown) or multi-unit loaded restorations (i.e., bridge, bars, overdentures). It is consists of Multiunit Straight Abutment, Multiunit Angled Abutment and Temporary Cylinder. The Multiunit Abutment has 4.8mm of diameter and consists of two kind of design that has three angles. The Multiunit Straight abutment has 0 degree and the Multiunit Angled abutment has 20 or 30 degree

The Eco Abutment and Multiunit Abutment are made from titanium alloy conforming to ASTM F136. It is provided non-sterile and is steam sterilized before use.

Non-Hex connection abutments are intended for multi-unit restorations only.

4. Indications for Use

<Eco Abutment>
The Eco Abutment is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation

<Multiunit Abutment>
The Multiunit Abutment is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation

5. Comparison of Technological Characteristics with the Predicate Device.

1) Eco Abutment

	Subject Device	Primary Predicate Device	Reference Device	Remark
Applicant	DIO Corporation	Nobel Biocare AB	DIO Corporation	-
Trade Name	Eco Abutment	On1 Concept	UV Active Implant system – Multi-unit Abutment	-
510(k) No.	K220253	K161655	K182194	-
Classification Name	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant (872.3640)	-
Product Code	NHA	NHA	DZE, NHA	-
Class	II	II	II	-
Indications For Use	The Eco Abutment is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.	The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.	The UV Active Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The narrow (Ø3.0, Ø3.3) implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. It is intended for delayed loading. The Regular (Ø3.8 ~ Ø5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The Wide (Ø6.0 ~ Ø6.4) implants can be placed with	Same

	Subject Device	Primary Predicate Device	Reference Device	Remark
			a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading	
Material	Eco Base Abutment, Eco Cemented post, Eco Angled post, Temporary Post : Ti-6Al-4V ELI (ASTM F136)	On1 Base, Temporary Abutment, On1 Healing Cap, Esthetic Abutment Titanium, Clinical Screws and Prosthetic Screws - Titanium vanadium alloy (ASTM F1472, ASTM F136) On1 Esthetic Abutment Zirconia – Y-TZP zirconium oxide (ISO 6872, ISO 13356)	Ti-6Al-4V ELI (ASTM F136)	Same
Design	- Post (Eco Cemented post, Eco Angled post, Eco Temporary post): Divided into Hex/Non-Hex connection -Eco Base Abutment: Divided into Hex/Non-Hex connection	2 piece (base placed either at time of implant placement or with final abutment) Abutment shape fixed	Multiunit Abutment: Divided into Hex/Non-Hex Connection	Similar; Except for its shape
Diameters (mm)	4.5/4.8/5.5/6.5	At base 4.8/5.3/6.5	4.8	Different but similar range
Length (mm)	Combined base abutment and post height Cemented post – 5.5/6.5/7.0/7.5/8.0/8.5/9.0/9.5/ 10.0/10.5/11.0/11.5/12.5 Angled post – 9.5/10.5/11.5/12.5/13.5 Temporary post – 5.5/6.5/7.0/7.5/8.0/8.5/9.0/9.5/ 10.0/10.5/11.0/11.5/12.5/13.5/14.5	Combined base and post height. Temporary Abut – 8.3/9.0 Esthetic Abut Ti – 8.2/9.0 Esthetic Abut Zi – 8.2/9.0	10.3/11.3/12.3/13.3	Similar; Longer range than predicate
Gingival heights (mm)	1.5/2.5/3.5/4.5/5.5	2.0/3.5	1.5/2.5/3.5/4.5/5.5	Same;
Angle	Eco Base abutment & Eco Cemented post: 0˚ Eco Base abutment & Eco Angled post: 6˚/12˚/18˚	No abutment angulation	0 ˚/ 20 ˚ / 30˚	Similar; Within range of reference device.
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)	Same
Type of Retention	Screw-retained or cemented retained	Screw-retained or cemented retained	Screw-retained or cemented retained	Same
Substantial Equivalence Discussion				

	Subject Device	Primary Predicate Device	Reference Device	Remark
Similarities The subject device is a two-piece abutment. It consists of Eco Base abutment and 3 types of post (Cemented, Angled and Temporary). The subject device has the same indications for use compared to the predicate device (K161655) and design (except for its shape), identical material composition and manufacturing methods by the same manufacturer compared to the reference device (K182194). The Indications for Use Statement has minor differences; however has the same intended use as being used with Endosseous dental implant to support a single or multiple prosthetic devices. **Differences** The diameter and lengths are different compared to the predicate device; however, the 4.5~6.5mm for the subject device and 4.8, 5.3 and 6.5mm for the predicate devices is comparable. The total length of 5.5 to 14.5 mm for the subject device is an extended range compared to the predicate devices. To account for these differences, fatigue testing was conducted in accordance with ISO 14801 to verify that subject device is substantially equivalent to the predicate devices. The results of fatigue testing were comparable between the predicate and subject device. **Discussion** The subject device is similar in fundamental scientific technology to the predicate device (K161655) in that they have been designed in compliance with FDA's Class II special controls guidance document root-form Endosseous dental implants and Endosseous dental implant abutment. There are slight mechanical differences between subject device and predicate devices which was evaluated through comparative performance testing. The documentation submitted in the premarket notification demonstrates that the subject device is substantially equivalent to the predicate devices. Therefore, we conclude that the Eco Base abutment is substantially equivalent to the predicate device.				

2) Multiunit Abutment

	Subject Device	Reference Device	Remark
Applicant	DIO Corporation	DIO Corporation	-
Trade Name	Multiunit Abutment	UV Active Implant system – Multi-unit Abutment	-
510(k) No.	K220253	K182194	-
Classification Name	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant (872.3640)	-
Product Code	NHA	DZE, NHA	-
Class	II	II	-
Indications For Use	The Multiunit Abutment is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.	The UV Active Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The narrow (Ø3.0, Ø3.3) implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. It is intended for delayed loading. The Regular (Ø3.8 ~ Ø5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The Wide (Ø6.0 ~ Ø6.4) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.	Similar – The reference device includes both implant bodies and abutments.
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Same
Design	Multiunit Straight / Multiunit Angled (Hex, Non-Hex) 	Multiunit Straight / Multiunit Angled (Hex, Non-Hex) 	Same
Diameters (mm)	4.8	4.8	Same
Cuff size (mm)	2.5/3.0/3.5/4.5/5.5/6.5/7.5	1.5/2.5/3.5/4.5/5.5	Similar; Subject device has longer range compared to reference device
Connected	Regular type	Regular type	Same

	Subject Device	Reference Device	Remark
fixture type			
Angle(˚)	0/20/30	0/20/30	Same
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)	Same
Type of Retention	Screw-retained or cement retained	Screw-retained or cement retained	Same

Substantial Equivalence Discussion

Similarities

The subject device has the same indications for use compared to the predicate device (K161655) and design, identical material and manufacturing methods and by the same manufacturer as the reference device (K182194). The Indications for Use Statement has minor differences; however has the same intended use as being used with Endosseous dental implant to support a single or multiple prosthetic devices.

Differences

The subject device is substantially equivalent to the indication for use, connected fixture type, design and angle as compared to the predicate devices, but includes additional specifications in order to cover different clinical situations. The subject device has additional cuff sizes as compared to the predicate devices. To account for these differences, fatigue testing was conducted in accordance with ISO 14081 to verify substantial equivalence with the predicate devices, and the subject device. The results of the fatigue testing were comparable between the predicate and subject device.

Discussion

There are slight mechanical differences between the subject device and predicate devices. These differences were evaluated through comparative performance testing. The documentation submitted it the premarket notification demonstrates that the subject device is substantially equivalent to the marketed devices.

Therefore, we conclude that the Multiunit abutment is substantially equivalent to the predicate device.

6. Summary of Non-clinical Testing

The results of the non-clinical testing demonstrate that the results have met the criteria of the standards, and the subject device is substantially equivalent to the predicate device.

Sterilization Validation

The subject device is provided non-sterile. Sterilization Validation has been performed in accordance with ISO 17665-1 and ISO 17665-2 for steam sterilization. Test results have demonstrated that the SAL of 10-6 was achieved and all testing requirements were met. Also, Sterilization Validation was conducted according to FDA Guidance *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".*

Biocompatibility

Biocompatibility tests were conducted in accordance with FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993-5, ISO 10993-10, ISO 10993-23, ISO 10993-11, ISO 10093-3, and ISO 10993-6. The Abutments have the identical nature of body contact, contact duration, material formulation, manufacturing processes, and sterilization methods compared to the reference devices, K182194 and K080559. No new issues of biocompatibility are raised for the subject devices.

Mechanical Properties

Fatigue testing was performed on the subject device including both the eco abutments and multiunit abutments in accordance with ISO 14801:2016 Dentistry-Implants-Dynamic fatigue test for Endosseous Dental Implants. The worst case scenario was chosen based on the FDA guidance *"Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".*

Comparative fatigue testing was also performed on comparative abutments cleared in K182194.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic. Eco Abutment and Multiunit Abutment in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry 0., Jana G. Delfino, and Sunder Rajan. 'Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices.' Journal of Testing and Evaluation 49.2 (2019): 783-795)., based on the entire system including all variations (all compatible implant bodied, dental abutments and, fixation screws) and material composition. Rationale addressed parameters per the FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

7. Summary of Clinical Testing

No clinical studies are submitted.

8. Conclusions

The Eco Abutment and Multiunit Abutment constitute a substantially equivalent medical device, meeting all the declared requirements of its intended use. These abutments have the same intended use and fundamental scientific technology as its predicate device. Therefore, Eco Abutment and Multiunit Abutment and its predicates are substantially equivalent.

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